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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,911	01/29/2007	Peter Budtz	030427-0109	4642
23428 7590 11/02/2010 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
MACAULEY, SHERIDAN R				
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1651				
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11/02/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,911

Applicant(s)

BUDTZ ET AL.

Examiner

SHERIDAN R. MACAULEY

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29, 31-41 and 43-55 is/are pending in the application.
- 4a) Of the above claim(s) 31, 50, 52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 31-41, 43-49, 51, 53 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/24/2010, 9/16/2010
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A response and amendment were received and entered on June 24, 2010. All evidence and arguments have been fully considered. Claims 1-26, 30 and 42 are cancelled. New claim 55 has been added. Claims 27-29, 31-41 and 43-55 are pending. Claims 31, 50, 52 and 54 are withdrawn due to a previous requirement for restriction. Claims 27-29, 31-41, 43-49, 51, 53 and 55 are examined on the merits in this Office action.

Information Disclosure Statement

2. The information disclosure statements submitted on June 24, 2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim objections have been withdrawn due to applicant's amendment.

Claim Rejections - 35 USC § 112

4. Rejections under 35 USC 112 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 102

5. Rejections under 35 USC 102 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 27-29, 32-41, 43, 44, 46-49, 51 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake et al. (US 3,862,005; reference cited in IDS) in view of Lynglev (US 2003/0113405 A1; reference cited in previous action). The

claims recite a process of producing lactobionic acid, said process comprising: i) adding to a dairy substrate a carbohydrate oxidase, ii) incubating said dairy substrate under conditions allowing the carbohydrate oxidase to convert lactose to lactobionic acid iii) maintaining pH during incubation in the range of 3.0 to 9.0 by addition of a weak base having a pK_b-value of at least 3.5 and then obtaining the lactobionic acid produced, whereby an increased yield and reduced reaction time are achieved in the enzymatic conversion of lactose to lactobionic acid. The claims further recite purifying the lactobionic acid to obtain a substantially pure lactobionic acid product. The claims recite the process further comprising the step of re-using the carbohydrate oxidase added in step i) for a new batch. The claims further recite that the base is calcium carbonate and that the dairy substrate is milk. The claims further recite that the pH in step iii) is maintained by adding the base during a time period that is sufficient to obtain a degree of conversion of lactose to lactobionic acid that is at least 2.5% higher than in a comparative control process wherein pH is not maintained during incubation. The claims further recite that the dairy substrate is milk, whey or fractions of whey or a lactose solution/suspension and that the carbohydrate oxidase is a microbial carbohydrate oxidase, specifically a carbohydrate oxidase obtained from a fungus belonging to the genus *Microdochium*, such as *Microdochium nivale* CBS 100236. The claims further recite that the amount of oxidase used is in the range from 0.1 to 1000 OXU per kg of dairy substrate. The claims further recite that the conditions in step ii) is selected from the group consisting of temperature, addition of oxygen, amount and type of carbohydrate oxidase, amount and type of catalase and time. The claims further

recite that the temperature is in the range of 0 to 80 degrees C. The claims further recite that pH in step iii) is maintained, by adequate addition of a base for a period of time sufficient to obtain a degree of conversion of lactose to lactobionic acid that is at least 5% higher than in a comparative control process where the only comparative difference is that during the incubation the pH is not maintained by adequate addition of a base. The claims further recite that the pH is maintained, by adequate addition of a base, at a pH from about 3.0 to 6.9 or from 7.1 to about 9.0. The claims further recite that the pH is maintained at the stable pH level for a time period that at least last until the oxygen level of the incubated dairy substrate has returned to more than 90% of the initial level. The claims further recite that the pH is maintained at the stable pH level as described herein for a time period from 30 minutes to 48 hours. The claims further recite that an optional purification results in a composition comprising at least 30% lactobionic acid or at least 90% lactobionic acid. The claims further recite that a starter culture comprising lactic acid bacteria is included in the process and wherein the starter culture may be added to the dairy substrate before or after the oxidase is added. The claims further recite that an integrated part of a food manufacturing process.

10. Miyake teaches a method for producing lactobionic acid wherein a carbohydrate oxidase (produced by a microorganism) is added to a lactose solution and incubated under conditions to convert lactose to lactobionic acid (col. 7, lines 1-12). The reference teaches that the pH may be adjusted or maintained in the range of 3.0 to 9.0 by the addition of calcium carbonate (col. 4, lines 1-34; col. 7, lines 1-12). The reference teaches that the pH may be maintained automatically by a pH controller (col. 6, lines 24-

25). Miyake teaches that a high yield of substantially pure lactobionic acid is obtained and purified (col. 7, lines 1-37). The reference teaches that the temperature may be 30 or 25 degrees and that the reaction may be carried out for 30 hours (col. 7, lines 1-37). The reference teaches that the pH at which to maintain the reaction is dependent upon the enzyme that is used (col. 4, lines 1-34); the cells used in the production of lactobionic acid are those prepared in example 1 (col. 7, line 3, col. 5, lines 16-34), which may be maintained at a pH of 6 (col. 6, lines 21-25). The reference teaches that the reaction is aerated; thus, the aeration level would remain at greater than 90% of its initial level throughout the fermentation (col. 7, lines 1-8).

11. Miyake does not teach the addition of the enzyme to dairy products. Miyake does not teach the addition of the specific enzyme recited in the claims. Miyake does not teach the use of an enzyme from *Microdochium*, the amount of enzyme that is added or that the enzyme is added before or after a starter culture.

12. Lynglev teaches a method for the production of a fermented dairy product (such as milk) wherein a carbohydrate oxidase (lactose oxidase) is added to a dairy substrate and the substrate is incubated to allow conversion of lactose to lactobionic acid (abstract, p. 2, par. 31). The method teaches that a starter culture is added to the substrate before the oxidase is added (pp. 1-2, par. 20-22). In the process of Lynglev, the oxidase may be from a species of *Microdochium*, specifically *Microdochium nivale* CBS 100236 (p. 1, par. 16-18, p. 2, par. 35). Although Lynglev discusses the use of 4-20 units of enzyme per 100 mL of dairy base, this amount would correspond to between 1 and 500 units per kg of dairy substrate (i.e., 20 units per 100 mL would correlate to

200 units per liter or per about 1 kg). At the end of the process of Lynglev, the pH is allowed to drop (p. 4, par. 72).

13. At the time of the invention, a method for the treatment of a lactose substrate using nearly the same process as is recited in the instant claims was known, as taught by Miyake. It was also known that a method for the production of lactobionic acid from a lactose substrate could use the enzyme recited in the claims and that the product could be acidified at the end of the process, as taught by Lynglev. One of ordinary skill in the art would have been motivated to combine these methods because Lynglev is directed to the improvement of the process of lactose products by the conversion of lactose to lactobionic acid and Miyake teaches that the production of lactobionic acid is enhanced by controlling the conditions of the reaction mixture (col. 1, line 60-col. 2, line 19). One would therefore recognize that the process of Miyake could be modified using the enzyme and conditions of Lynglev. Although the references do not teach the specific reuse of the enzyme for a new batch, Lynglev teaches that a yogurt culture may be used and teaches fermentation methods whereby yogurt products are produced (p. 3, par. 33, 42); thus, one of ordinary skill in the art would have recognized that the enzyme from the culturing of microorganism during the fermentation of a dairy product could be reused in another fermentation. One of ordinary skill in the art would have had a reasonable expectation of success in performing such a method because both references are directed to the fermentation of a dairy product using similar processes. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

14. Claims 27-29, 31-41, 43-49, 51, 53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake et al. (US 3,862,005; reference cited in IDS) in view of Lynglev (US 2003/0113405 A1; reference cited in previous action) as applied to claims 27, 28, 32-41, 43, 44, 46-49, 51 and 55 above, and further in view of Rand (Journal of Dairy Science, 1974, 58:1144-1150). Claims 27-29, 32-41, 43, 44, 46-49, 51 and 55 are discussed above. The claims further recite that a catalase is added in step (i) of the process in an amount that decreases the amount of hydrogen peroxide produced during conversion of lactose. The claims further recite that the amount of catalase added is in an amount sufficient to obtain an at least 10% decrease in the concentration of hydrogen peroxide as compared to a control process where the only comparative difference is that catalase is not added. The claims further recite that essentially all of the suitable amount of oxygen required in step (ii) is obtained by extra addition of a suitable amount of hydrogen peroxide and wherein the catalase generates the required oxygen from the available hydrogen peroxide.

15. The teachings of Miyake and Lynglev have been provided in the rejections above. As discussed above, it would have been obvious to combine the teachings of the references to arrive at nearly all elements of the claimed invention. Neither reference, however, teaches addition of catalase and hydrogen peroxide in order to add oxygen to the reaction.

16. Rand teaches the addition of oxygen in the form of hydrogen peroxide in the presence of a catalase in order to regenerate the oxidase enzyme (see, for instance, p.

1144, col. 1). One of ordinary skill in the art would have been motivated to combine these teachings because the reference teaches that the addition hydrogen peroxide and catalase was an efficient system for the addition of oxygen throughout the milk substrate in a process for the oxidation of lactose. One would therefore have been motivated to add the components taught by Rand to the process of Miyake and Lynglev and could reasonably expect the added oxygen to improve the rate of the reaction, since the reaction is oxygen-dependent. Although the references do not teach what portion of the oxygen added would be from hydrogen peroxide and what portion would be from aeration, it is noted that aeration and hydrogen peroxide/catalase systems were both known to be suitable aeration methods for the regeneration of an oxidase; thus, one of ordinary skill in the art could have achieved the claimed system with a reasonable expectation of success. One of ordinary skill in the art would have had a reasonable expectation of success in performing such a method because the references are directed to the fermentation of a dairy product using similar processes. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

17. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 27-29, 31-41, 43-49, 51, 53 and 55 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 11/621819 in view of Miyake et al. (US 3,862,005; reference cited in IDS) and Lynglev (US 2003/0113405 A1; reference cited in previous action). The claims of the copending application are directed to a method of making a lactobionate product that meets all of the limitation of claim 1 of the instant claims. Those elements of the claims under examination that are not disclosed in the copending application are taught by the cited references, as discussed above. The motivation to combine the method recited in the claims of the copending application and the references to arrive at the claimed process are discussed in the above rejections. Therefore, the claims of the instant application are rendered obvious and therefore

unpatentable in view of the claims of the copending application and the cited references.

20. This is a provisional obviousness-type double patenting rejection.

Response to Arguments

21. Applicant's arguments, filed June 24, 2010, with respect to the Ullman reference have been considered but are moot in view of the new ground(s) of rejection.

22. Applicant's further arguments have been fully considered but they are not persuasive. Applicant argues that the claimed invention provides an unexpected advantage over the teachings of the prior art. Specifically, applicant argues that the advantage is the conversion of time of approximately 4.5 hours. However, this aspect of applicant's invention is not recited in the instant claims. Furthermore, applicant has not shown that this advantage encompasses to all embodiments of the claimed invention or whether this result was obtained using a distinct set of variables. Therefore, applicant's argument that the claimed invention presents an unexpected result has not been found to be persuasive.

23. This, applicant's arguments have been fully considered, but they have not been found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A. Davis/

Primary Examiner, Art Unit 1651